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10/648,536	08/25/2003	Robert Owen Lockerbie	B0175-US02	4649

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EXAMINER	
LEE, JAE W	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,536	LOCKERBIE ET AL.	
	Examiner	Art Unit	
	JAE W. LEE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-14,16-19,21 and 23* is/are rejected.

7)☒ Claim(s) *15 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

In response to the previous Office action, a non-final rejection (mailed on 09/04/2008), Applicants filed an amendment to claims on 12/01/2008. Claims 2, 3 and 20 are canceled, and amended Claims 1, 4-6, 9-12, 15, 16 and 21-23. Thus, Claims 1, 4-19 and 21-23 are at issue and present for examination.

Applicants' arguments filed on 12/01/2008, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

The previous objection of Claim 5 for reciting the phrase "selected from the group consisting essentially of...," is withdrawn because Applicants have deleted the word "essentially".

The previous objection of Claims 1, 10, 11, 15, 16, 21 and 23 for the use of terms "riboflavin photosensitizer," "riboflavin," and/or "photosensitizer" is withdrawn by virtue of Applicants' amendment.

The previous objection of Claim 21 for the recitation of "pathogen reduced" is withdrawn by virtue of Applicants' amendment.

The previous objection of Claim 21 because the step of "damaging" can be improved with respect to clarity, is withdrawn by virtue of Applicants' amendment.

Claims 15 and 22 are objected to because of the following informalities:

Claims 15 and 22 are objected to for depending from a rejected claim.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

The previous rejection of Claims 4, 6, 9, 22 and 23 for lacking antecedent basis for the term "the fluid" is withdrawn by virtue of Applicants' amendment.

The previous rejection of Claims 11 (12-19 dependent therefrom) for reciting the phrase, "substantially maintaining the damage to the nucleic acids," is withdrawn because the specification on page 8, lines 1-5, defines the phrase as below:

> "[s]ubstantially maintaining the damage means that any damage sustained by the nucleic acids of pathogens is maintained over time so that when the blood product, which has been treated with riboflavin and light is transfused into a recipient, the inactivated pathogen will not self-repair the damaged nucleic acids, and reproduce in the transfusion recipient."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for a process comprising steps of: adding to a solution containing pathogenic white blood cells, bacteria and/or viruses, 50 μM of isoalloxazine comprising riboflavin; irradiating a solution containing said pathogenic white blood cells, bacteria and/or viruses, 50 μM of isoalloxazine with light, at wavelength of 320 nm and intensity of 7 J/cm^2, to activate isoalloxazine to cause single strand and double strand breaks to the deoxyribonucleic acids and ribonucleic acids of said pathogenic white blood cells, bacteria and/or viruses; wherein said strand breaks caused by the isoalloxazine and light, at wavelength of 320 nm and intensity of 7 J/cm^2, is maintained during storage of the solution after irradiation, does not reasonably provide enablement for a process for *preventing self-repair* of nucleic acid of pathogenic white blood cells, bacteria and/or viruses which may be contained in blood components comprising the steps of: adding to the blood components riboflavin acting as a photosensitizer; irradiating the blood components and riboflavin acting as a photosensitizer with light in a visible or UV range at an appropriate wavelength to activate the riboflavin acting as a photosensitizer to fragment the nucleic acid of the pathogenic white blood cells, bacteria and/or viruses to cause permanent damage to the nucleic acid; *preventing self-repair* of the nucleic acid; and wherein the permanent damage to the nucleic acid caused by the photosensitizer and light is maintained over time such that the pathogenic white blood cells, bacteria and/or viruses will not reproduce in the blood components (italicized for added

emphasis). Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1, 4-19 and 21-23. In response to this rejection, Applicants have amended Claims 1, 4-6, 9-12, 15, 16 and 21-23, and traverse the rejection as it applies to the newly amended claims.

Applicants argue that as described on page 7, beginning on line 27, "repair is defined as the molecular processes that are the basis for pathogen reactivation. Reactivation, or the synonymous term recovery, is defined as the regaining of, by a damaged pathogen, the capability to propagate..." Fig. 7 shows a graph of log/mL virus reactivation in response to riboflavin concentration. Applicants further argue that as can be seen from Fig. 7, irradiation of virus with riboflavin and light prevents reactivation of viral DNA. Applicants believe this data enables Applicants independent claim 1 and the dependent claims that depend therefrom. As described in Example 3, beginning on page 12, exposure of the white blood cells (as represented by Jurkat cells) to riboflavin and light fragmented the nucleic acids. Fragmenting the DNA causes damage to the nucleic acids of the white blood cells.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Contrary to Applicants' allegation, Figure 7 shows that the "reactivation" or "repair" of lambda-phage virus is NOT prevented (see positive values as high as ~84% on the vertical axis at concentrations below 300 μm Riboflavin

in Figure 7). As such, the scope of the claims, which include "preventing self-repair" of the fragmented DNA damages of pathogenic white blood cells, bacteria and/or viruses in the blood components as previously explained, is NOT commensurate with the enablement provided by Applicants, and therefore, the specification does not enable one of skill in the art to make and use the invention as claimed. For the reasons provided herein and in the previous office actions, the rejection under this statute is maintained.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6-8, 11-14, 16-19, 21 and 23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Goodrich et al. (USPN 6,258,577).

The rejection was stated in the previous office action as it applied to previous claims 1, 6-8, 11-14, 16-19, 21 and 23. In response to this rejection, Applicants have amended Claims 1, 6, 11, 12, 16, 21 and 23, and traverse the rejection as it applies to the newly amended claims.

Applicants argue that the claimed limitation "prevention of self-repair of the nucleic acids" is not inherent in the Goodrich disclosure. There is nothing in the Goodrich reference to suggest that nucleic acids exposed to riboflavin and light are unable to self-repair. As set forth in EMI Group North America, Inc. v. Cypress Semiconductor Corp, 268 F.3d 1342, 60 USPQ2d 1423 (Fed. Cir. 2001) which referenced Continental Can Co. v. Monsanto Co. "[t]o serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. First, it is noted that Applicants' argument is irrelevant regarding claims 11-14, 16-19, 21 and 23 because these claims no longer recite "to prevent re-activation" or "to prevent ... from reproducing". As such, Goodrich et al. do not need to disclose such limitations.

Furthermore, while Goodrich et al. do not specifically recite "prevention of self-repair of nucleic acids from pathogenic white blood cells, bacteria and/or viruses" as recited in claims 1 and 6, this limitation is inherent to the method disclosed by Goodrich et al. *at least with regard to viruses* because these identical method steps produce such effect *as evidenced by applicant's specification* (emphasis added). In support of this notion, Figure 7 and page 14 of the specification, disclose that the lambda phage virus irradiated with 320 nm UVB at 0.08 J/cm^2 at concentrations above 300 μM riboflavin, was not re-activated when it was incubated with E. coli host cells for 20 minutes to allow for viral absorption after the irradiation step. Therefore, the methods described by Goodrich et al., which also requires the identical steps recited in the claims, would inherently result in the prevention of self-repair of viruses, and no extrinsic evidence is required to prove this inherent effect. For the reasons provided herein and in the previous office actions, the rejection under this statute is maintained.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-8, 10-14, 16-19, 21 and 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Goodrich et al.[1] (USPN 6,258,577) in view of Goodrich et al.[2] (WO/2002/096471, VIRAL INACTIVATION PROCESS USING ANTIOXIDANT).

The rejection was stated in the previous office action as it applied to previous claims 1, 4-8, 10-14, 16-19, 21 and 23. In response to this rejection, Applicants have amended Claims 1, 4-6, 10-12, 16, 21 and 23, and traverse the rejection as it applies to the newly amended claims.

Applicants argue that Goodrich[1] does not teach or suggest "irradiating the blood components and riboflavin with light to fragment the nucleic acid of the pathogenic white blood cells, bacteria or viruses to prevent self repair of the nucleic acids." Neither does Goodrich[2]. Goodrich[2] discloses an additive solution for irradiating a blood component comprising riboflavin and a quencher. It does not suggest that irradiating blood components with the additive solution would prevent the self-repair of the nucleic acids. Applicants allege that one skilled in the art would not assume that just because the nucleic acids of pathogens was exposed to riboflavin and light, that the damage was maintained over time such that the pathogens will not reproduce in the blood components as in Applicants' current invention.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. First, it is noted that Applicants' argument is irrelevant regarding claims 11-14, 16-19, 21 and 23 because these claims no longer recite "to prevent re-activation" or "to prevent ... from reproducing". As such, Goodrich et al. do not need to disclose such limitations.

Furthermore, while Goodrich et al. do not specifically recite "prevention of self-repair of nucleic acids from pathogenic white blood cells, bacteria and/or viruses" as recited in claims 1 and 6, this limitation is inherent to the method disclosed by Goodrich et al. *at least with regard to viruses* because these identical method steps produce such effect *as evidenced by applicant's specification* (emphasis added). In support of this notion, Figure 7 and page 14 of the specification, disclose that the lambda phage virus irradiated with 320 nm UVB at 0.08 J/cm^2 at concentrations above 300 μM riboflavin, was not re-activated when it was incubated with E. coli host cells for 20 minutes to allow for viral absorption after the irradiation step. Therefore, the methods described by Goodrich et al., which also requires the identical steps recited in the claims, would inherently result in the prevention of self-repair of viruses, and no extrinsic evidence is required to prove this inherent effect. For the reasons provided herein and in the previous office actions, the rejection under this statute is maintained.

Conclusion

Claims 1, 4-14, 16-19, 21 and 23 are rejected and Claims 15 and 22 are objected to for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on M-F between 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656

/Rebecca E. Prouty/
Primary Examiner,
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